

REMARKS**Claim Rejections - 35 U.S.C. § 103**

In the Office Action dated December 21, 2004, the Examiner rejected claims 1, 3-11, 15-16, 18-21, and 26-30 under 35 U.S.C. § 103(a) as unpatentable over *Mayaud* in view of *Kaker*; and rejected claims 12-14, 17, and 22-25 under 35 U.S.C. § 103(a) as unpatentable over *Mayaud* in view of *Kaker*, and further in view of *nevoca*. To establish a prima facie case of obviousness, three basic criteria must be met, namely:

- 1) There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings;
- 2) There must be a reasonable expectation of success; and
- 3) The prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure.¹

The pending claims contain three independent claims, namely claims 1, 22, and 24. These three claims have many of the same elements. Therefore, as per the Examiners' rejections all of the pending independent claims are dealt with collectively.

The Examiner's rejection relies on U.S. published application No. 2001/0037218 A1 to *Kaker et.al.*, filed on March 30, 2001. The present application, however, was filed on August 22, 2000, and, therefore, predates *Kaker*'s non-provisional filing date. Accordingly, any rejection based on *Kaker* must make use of the disclosure contained in *Kaker*'s Provisional application, application No. 60/197,416, filed on April 14, 2000. In light of the above, this response only refers to *Kaker*'s Provisional application No. 60/197,416 (hereinafter "*Kaker*"), attached hereto as Exhibit A.

Each of the Examiner's rejections will now be addressed in detail.

The Examiner states that:

[a]s per claim 1, *Mayaud* teaches a method for renewing a prescription for a pharmaceutical via an electronic network,

¹ *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

comprising the steps of: *computer generating a prescription renewal request for the renewal of a prior prescription* (see column 19, lines 48-53 and lines 63-67);

The portions of *Mayaud* relied upon by the Examiner are repeated below for ease of reference:

Prescription history zone 43 displays those historical prescription details that may be relevant to a current prescription and has a Condition field 64, a Drug field 66, a Size field 68 a Dosing field 70, a generic flag 72, an Expires field 74 and a Mine field 76, in which the various characteristics of patient Mary Harrington's previous prescriptions are listed.

Multiple lines of the selected patient's prescription history are listed in patient history zone 43 in the middle of the screen for convenient review by the physician-user, and possible renewal, with scrolling or paging of extensive histories.

Mayaud is a physician based tool that does not require receiving requests for renewed prescriptions from a system that monitors expiration dates. Although *Mayaud* discloses renewal of a prescription, *Mayaud* does not disclose generating a prescription renewal request. The prescription renewal request is a request that is sent to a prescriber requesting that a prescription be renewed. The prescription renewal request is not the same as the renewal prescription, which is separately claimed in the independent claims. Unlike the prescription renewal request, which is sent to a prescriber, the renewal prescription is sent from the prescriber to the dispenser, who then fills the renewal prescription, *i.e.*, dispenses the pharmaceuticals. *Mayaud* only teaches generating a renewal prescription, but not a prescription renewal request. This is an important distinction between the references, as *Mayaud* does not teach a separate system that monitors the expiration date of prescriptions and transmits a prescription renewal request to the prescriber requesting a renewal prescription based on the monitoring. Accordingly, *Mayaud* cannot anticipate this element of independent claim 1, as it does not disclose, teach, or suggest generating a prescription renewal request.

The Examiner further states that *Mayaud* teaches:

receiving a renewal prescription, in response to said prescription renewal request, from a prescriber (see column 20, lines 50-60);

As described above, the system in *Mayaud* never receives a prescription renewal request and, therefore, cannot generate a renewal prescription in response thereto.

The Examiner further states that:

Mayaud does not explicitly teach computer monitoring an expiration date of a prescription, generating the renewal request based on the computer monitoring, and transmitting the prescription renewal request to a prescriber.

For these elements, the Examiner relies upon *Kaker*. *Kaker* discloses a system and method completely unrelated to the methods claimed in the present application. In particular, *Kaker* is directed to automating the generation of forms for prescription assistance programs. *Kaker* provides computer software that is “designed to provide and track prescription assistance for indigent consumers using the programs provided by the pharmaceutical manufactures.” *Kaker*, Provisional app., pg. 4. These assistance programs are provided by many pharmaceutical manufacturers to supply medications at a reduced cost (or no cost) to indigent patients. A problem with these assistance programs is that the manufacturer's program information is not readily available to indigent persons at whom the programs are directed. *Id.* *Kaker* proposes to solve this problem by computerizing the generation of the forms provided by the manufacturers; collecting a list of available drugs and participating pharmaceutical manufacturers; maintaining records of the application date, approval date, and drug cost; and providing the patient with a renewal form containing the expiration date of their prescription printed thereon. *Id.* This form is then mailed by the indigent patient to the pharmaceutical company's assistance program. Accordingly, it is clear that the subject matter of *Kaker* is completely unrelated to the present invention.

In particular, the Examiner states that:

Kaker teaches a system that computer monitors an expiration date of a prescription (see paragraph 146);

Kaker, however, merely calculates the Expiration date in response to a user pressing the calculate dates button. *Kaker*, para. 1, pg. 12. The calculated Expiration date “lets the client know that their pill will run out on that day.” *Id.* *Kaker* also teaches calculating a renewal date, which “is a date in which to remind the client that it is time to mail in the renewal application so that they will not run out of meds.” *Id.* The “renewal date... gives the client a week leeway time in order to get the application letter back on time.” *Id.* Once these dates are calculated, and the necessary fields filled-in, a user prints out the form and hands it to the patient. *See Kaker*, ultimate para., page 9. The patient then returns home with the form. On the “renewal date,” the patient mails the application form to the pharmaceutical manufacturer to obtain the medication.

In contrast, the above-referenced application claims the step of monitoring expiration dates of prescriptions. The term “monitoring” as used in the present application is used

consistently with the ordinary dictionary definition of this term and means “to test or sample on a regular or ongoing basis.” *See* American Heritage Dictionary, 3rd edition, (1997), p 881. Therefore, the claims of the above-referenced application require the methods to continuously review prescriptions for upcoming expiration dates. Monitoring is not simply a calculation of an expiration date through a fixed formula and monitoring does not occur following a user pressing a “calculate dates” button, such as described in *Kaker*. Monitoring requires a computer programmed to oversee at least one prescription and keep track of it throughout its lifecycle on an ongoing basis. In other words, the monitoring is intertwined with the events that occur to a prescription over time, such as refills, prescription renewals, and prescription alterations.

Kaker does not teach any system that computer monitors an expiration date of a prescription. Rather, *Kaker* discloses, in response to a users request, a one time calculation of when a future expiration will occur and/or the renewal date when the patient should mail in their form. Accordingly, *Kaker* does not disclose, teach, or suggest computer monitoring of an expiration date.

The Examiner further states that *Kaker* teaches a system that:

generates a renewal request prior to said expiration date based on said computer monitoring and without patient involvement (see paragraph 147);

Although *Kaker* teaches generating a form for prescription assistance, *Kaker* in no way discloses, teaches, or suggests generating a prescription renewal request that requests a renewal prescription (and not the medication itself). Furthermore, as there is no computer monitoring in *Kaker*, such that, a prescription renewal request cannot be generated based on the computer monitoring.

Still further, the Examiner states that *Kaker* teaches a system for:

transmitting the prescription renewal request to a prescriber (see paragraph 155).

As *Kaker* does not disclose generating a prescription renewal request, it simply follows that *Kaker* cannot disclose transmitting a prescription renewal request to a prescriber. Furthermore, *Kaker* does not disclose, teach, or suggest any type of prescriber at all. Rather, *Kaker* teaches mailing a letter containing a request for prescription assistance to a pharmaceutical manufacturer's prescription assistance program. This in no way teaches or suggests transmitting a prescription renewal request to a prescriber.

For at least the reasons stated above, the combination of *Mayaud* and *Kaker* fail to teach every limitation of the independent claims.

The Examiner further states that

[I]t would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate these features into the system of *Mayaud*. One of ordinary skill in the art would have been motivated to incorporate these features for the purpose of aiding physicians in tracking and monitoring prescription drugs needed by indigent patients.

Despite the references not disclosing or teaching the combination of all the elements of the independent claims, Applicants respectfully disagree with that Examiner that it would have been obvious to combine the references of *Mayaud* and *Kaker*. The only similarity between the two references is that they both broadly relate to pharmaceuticals. As described above, *Mayaud* is directed to a physician's prescription management system, while *Kaker* is directed to software for generating forms that are printed and mailed to a prescription assistance program by indigent patients. *Mayaud* does not disclose, teach, or suggest the combined use with a pharmaceutical manufacture's prescription assistance programs, while *Kaker* does not disclose, teach, or suggest the generation of renewal prescriptions at all. Accordingly, there is no suggestion or motivation in either *Mayaud* or *Kaker* to combine reference teachings.

For at least the reasons stated above, independent claims 1, 22, and 24 and all the claims that depend therefrom (claims 3-21, 23 and 25-30) cannot be unpatentable over the combination of *Mayaud* and *Kaker*.


CONCLUSION

In view of the foregoing, it is respectfully submitted that the application is now in condition for allowance. However, should the Examiner believe that the claims are not in condition for allowance, the Applicant encourages the Examiner to call the undersigned attorney at 650-843-7519 to set up an interview.

If there are any fees or credits due in connection with the filing of this Amendment, including any fees required for an Extension of Time under 37 C.F.R. § 1.136, authorization is given to charge any necessary fees to Deposit Account No. 50-0310 (order No. 061018-0008-US). A copy of this sheet is enclosed for such purpose.

Respectfully submitted,

Date: April 14, 2005



45,645

Dion M. Bregman (Reg. No.)

MORGAN, LEWIS & BOCKIUS LLP

2 Palo Alto Square

3000 El Camino Real, Suite 700

Palo Alto, California 94306

(650) 843-4000